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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,546	08/13/2001	Neil H. Bander	266/186	3868
26161	7590	11/04/2004	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			NICKOL, GARY B	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/929,546	Applicant(s) BANDER, NEIL H.	
	Examiner Gary B. Nickol Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 58-69, 72, 73, 84-111 and 113 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 58-69 is/are allowed.
- 6) ☒ Claim(s) 11, 72, 73, 84 and 113 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Re: Bander *et al.*

Date of priority: 05/06/1996

Response to Amendment

The Amendment filed 08-16-04 in response to the Office Action of 05-18-04 is acknowledged and has been entered.

Claims 58-69, 72-73, 84-111, and 113 are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Rejection Maintained:

Claims 72-73, 84-11, and 113 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record and for the reasons set forth below.

Applicants argue (Response, 08-16-04, page 9) that the written description requirement is met if the specification shows that an applicant was in possession of the claimed invention at the time of filing. Applicants further refer to several court decisions: *in Re Smith, Purdue Pharma*

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v. Faulding, Inc., and In re Wright which, taken out of context, appear to conclude that the original disclosure need not provide literal support or exact wording for claimed subject matter. In this particular instance, applicants note that the claimed invention involves a method that uses an antibody having a specific feature: “it competes for binding PSMA with a specific, disclosed antibody, namely E99, J591, J415, or J533”. Applicants further provided a Declaration by Abbie Celniker under 37 CFR 1.132 which proposes that the specification, on page 27, lines 26-35, indicates that Applicant was in possession of antibodies that compete for binding with J415, J591, J533 or E99.

Applicant’s arguments and the Declaration have been carefully considered, but are not found persuasive. As set forth previously, the specification only provides a written description and indicates possession of a genus of antibodies that bind to the extracellular domain of PSMA and four such monoclonal antibodies, or *species* of the genus, e.g. E99, J591, J415, or J533.

The rejected claims, (i.e. those covering a class of antibodies that “compete for binding” to E99, J591, J415, or J533) are not representative of the above genus or species. In particular, competing antibodies represent those antibodies that have yet to be discovered and that comprise the same binding properties as E99, J591, J415, or J533. It is applicant’s contention that they are in possession of all such competing antibodies from the paragraph on page 27, lines 26-35 (*note to applicant-- this passage appears to be on page 32, lines 28+*) in the disclosure which refers to the conjugation of drugs to antibodies. This argument has been considered but is not found persuasive, as it appears that the alleged support has been taken out of context. The passage that applicants refer to pertains to biological agents conjugated to prodrugs- such as antibody conjugates. Prodrugs are inactive drugs. In the instant case, the conjugated prodrug becomes

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activated (page 32, line 34) “only when in *close* proximity with a prodrug activator”. Thus, the fact that a preferred embodiment of a prodrug/prodrug activator scenario is one in which the biological agent binds in close proximity to one another (i.e...to non-competing sites) on the antigen is *not* surprising given the fact that said activators must be nearby to activate the prodrug. In contrast, however, it would be surprising and quite complex to conceive of administering biological agents conjugated to prodrugs and or prodrug activators that bind to *competing* sites on an antigen because such sites are indicative of the same epitope. Hence, the administration of biological agents (for the purposes of activating a prodrug) that bind to competing sites would effectively reduce the probability that a prodrug would be activated. Thus, applicants alleged support for the inclusion of “competing” sites is not found persuasive because there is no contextual nexus that adequately provides support for the newly amended claims. The fact that one mechanism of binding is preferred does not necessarily provide possession for a completely different functional and mechanistic effect, i.e. competing antibodies. This reasoning further extends to applicants arguments that the specification discloses what constitutes a competing site and what constitutes a non-competing site by stating that “whether two biological agents bind to competing or non-competing sites can be determined by conventional competition binding assays.”. Again, such a passage refers to the administration of *non-competing* antibodies wherein the next sentence (page 33, line 3) recites: “Thus, for example, the first biological agent can be one of J591, J533, and E99, and the second biological agent can be J415. Alternatively, the first biological agent can be J415, and the second biological agent can be one of J591, J533, and E99.” Thus, there is never a suggestion or a contemplation to possess or use

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antibodies that recognize the same epitope or compete with E99, J415, J533 and J591. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

Claims 58-69 are allowable.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

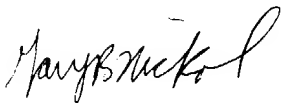
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.
Primary Examiner
Art Unit 1642

GBN



GARY NICKOL
PRIMARY EXAMINER